

REMARKS

Applicants respectfully request consideration of the foregoing amendments and the following comments upon continued examination of the present applicaiton.

I. Status of the Claims

Claim 1 has been amended for greater clarity and with exemplary support in the original specification, *e.g.*, at page 1, paragraph [0002]. Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-57 will be pending, with claims 11, 12 and 18-55 withdrawn from consideration.

II. Rejection of Claims under 35 U.S.C. §103(a)

Claims 1-10 and 56-57 remain rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,632,996 to Ramirez et al. (“Ramirez”) in view of U.S. Patent No. 4,917,816 to Self (“Self”); claims 1-10, 14-16, 56 and 57 remain rejected under 35 U.S.C. §103(a) over Ramirez, Self and U.S. Patent No. 5,719,197 to Kanios et al. (“Kanios”); and finally, claims 1-10, 13-17, 56 and 57 remain rejected under 35 U.S.C. §103(a) over Ramirez, Self, Kanios and U.S. Patent No. 5,399,353 to Bartnick et al. (“Bartnick”). Applicants respectfully traverse each rejection.

The claimed invention relates to a nanoparticulate composition comprising benzoyl peroxide particles having an effective average particle size of less than 2000 nm and at least one surface stabilizer adsorbed to or associated with the surface of the benzoyl peroxide particles. The cited art fails to teach or suggest the surface stabilizer of the claimed composition.

The Examiner asserts that colloidal silicon dioxide of Ramirez’s disclosure renders the surface stabilizer of the claimed composition obvious. Final Office Action, page 2, lines 13-15. Ramirez describes a composition comprising, *inter alia*, silicone-copolyol or silica (*see* column 4, lines 40-41). Ramirez fails to disclose any physical relationship between the benzoyl peroxide particles and silicone-copolyol or silica. There is no indication that either silicone-copolyol or

silica can be adsorbed on or associated with the surface of the benzoyl peroxide particles. This is because Ramirez's methodology entails *solubilizing* benzoyl peroxide particles in alkylbenzoate. Once the benzoyl peroxide particles are solubilized, there are no solid particles or any particle surface available for silicone-copolyol or silica to adsorb to or to associate with.

The Examiner contends that "the plain use [of the] term "associated [with]" is broad" (final Office Action). Claim 1 has been amended for greater clarity by reciting that the surface stabilizer is adsorbed to or associated with the surface of the benzoyl peroxide particles. The term "adsorption" refers to the fact that the surface stabilizer is retained at the surface of the active agent; there is no chemical bond, such as a covalent bond, between the surface stabilizer and the active agent.

Moreover, the technology of solubilizing the benzoyl peroxide particles as represented by Ramirez is different from that of obtaining a nanoparticulate benzoyl peroxide composition as prescribed by the claimed invention. The former runs against the problem of solving insolubility and the risk of leaving trace amount of chemical solvents. As such, the claimed invention has the advantages of minimum risk of side effects possibly caused by the organic solvent and lower manufacturing cost by eliminating an extra step to remove the organic solvent.

The Examiner further contends that "the Applicant has not . . . exclude[d] alkylbenzoate (AB) as a possible surface stabilizer" (final Office Action, page 2, lines 16-17). As submitted in the response filed on April 21, 2009, alkylbenzoate is used as a *solvent* in Ramirez's composition to dissolve the benzoyl peroxide particles. In contrast, the benzoyl peroxide particles in the claimed composition are in solid phases, such as a crystalline phase, an amorphous phase and a semi-crystalline phase. Clearly, the benzoyl peroxide particles in the claimed composition are not solubilized by the surface stabilizer. Rather, the surface stabilizer is adsorbed to the surface of the solid particles of benzoyl peroxide.

Self is cited for the alleged teaching of a particle size of between 2 microns and 5 microns. Kanios is cited for the alleged teaching of bioadhesive compositions. Last, Bartnick is cited for the alleged teaching of PVP and lysozyme as surface stabilizers. However, none of these additional references compensate for the deficiencies of Ramirez. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness by meeting all the claim limitations.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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